

USSN 09/211,507

Response After Final

REMARKS

Reconsideration of the pending claims based on the amendments and remarks presented herewith, is respectfully requested.

Claims 1, 2, 4-6, 9-11, 35, and 39-44 are pending.

Claims 9 and 10 have been amended. The amendment of Claims 9 and 10 is intended to merely clarify the claims, however the scope of the claims is intended to be the same after the amendment as it was before the amendment. No new matter is added with the amendments.

Rejections under 35 U.S.C. § 112(1).

The Examiner maintains the rejection of Claims 1, 2, 4-6, 9-11, 35, and 39-44 under Section 112(1) for lack of enablement. This rejection is respectfully traversed.

The Examiner has admitted that the specification is enabling for altering blood flow to the vagina by inhaling "the particular commercial odorants...or mixtures thereof instantly demonstrated," disclosed at page 12, lines 1-13.

The Examiner maintains that the claims are enabled only for "the instantly disclosed particular commercial odorants and mixtures thereof" — not for "undefined and/or non-commercial odorants thereof." The Examiner maintains this position stating that "it would take undue experimentation without a reasonable expectation of success for one of skill in the art to prepare and use an article of manufacture having the unusual disclosed/claimed functional effect, other than using one of the particular demonstrated commercial odorants or mixtures thereof..."

The Examiner asserts that the instantly claimed odorants are highly subjective with respect to the actual odors being encompassed, stating that a given recipe of pumpkin pie or banana nut bread varies according to the ingredients, baby powder varies by commercial manufacturer, cucumber varies based upon the brand, species, age/ripeness, geographic location in which it is grown, etc., licorice-based odorants such as Good and Plenty™ have a distinct odor from that of some other licorice based products such as anise, and chocolate such as milk chocolate has a distinct odor from dark chocolate. The Examiner also asserts that the use of other odorants would be highly unpredictable between females and should be limited to the

MKE/789324.1

USSN 09/211,507

Response After Final

commercially identified odorants because the same mixture of odorants can cause an increased blood flow to the vagina in some females and a decreased blood flow to the vagina in other females. The Examiner also cites to Doty (Philadelphia Sensorics, 1983) to show that variables such as occupation, general health, psychological state and age, make the use of other odorants highly unpredictable between females.

The Examiner has provided no good basis for his position.

First of all, the Examiner erroneously contends that the claims encompass "*any undefined odorant* and/or the various mixture of *subjective odorants*" (emphasis added).

The claims are limited to odorants that alter blood flow to the vagina and thus do not call for just any odorant. Furthermore, the pending claims are directed to methods utilizing *specified mixtures of odorants*: a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants.

One of ordinary skill in the odorant arts would readily ascertain particular odorants that fall within the scope of the claim other than the particular demonstrated commercial odorant mixtures. Indeed, one of ordinary skill in the odorant arts would be able to ascertain whether a substance had a chocolate aroma, a licorice aroma, a banana nut bread aroma, a cucumber aroma, a lavender aroma, or a baby powder aroma, regardless of whether the substance was the commercial source disclosed, or another synthetic or natural source.

The character of the particular odorants recited in the claims is well-delineated, commercial source odorants are identified, and a working example is provided that would enable an art worker to obtain and employ such compounds as broadly as they are claimed, particularly based on the knowledge in the odorant arts. Clearly, one of ordinary skill in the odorant arts would be fully enabled to practice Applicant's invention utilizing both synthetic and natural odorant mixtures from a variety of sources.

Furthermore, the Examiner assertions based on Doty are without any basis.

Doty (Philadelphia Sensorics, 1983) discloses a test for identifying odorants (the "Smell Identification Test"), in which a subject inhales an odorant and then attempts to identify it. Doty described a series of experiments to develop the odor identification test. Doty describes (at

MKE/789324.1

USSN 09/211,507

Response After Final

page 3) conducting five initial experiments to develop the Smell Identification Test™: Exp. 1: selection of stimuli; Exp. 2: *examination of influence of variables such as the age, gender, and ethnic background of subjects on the scores of the developed Smell Identification Test™*; Exp. 3: use of the test to discriminate among person with olfactory disorders; Exp. 4: determining test-retest reliability; and Exp. 5: comparison of test scores to results from a traditional detection threshold procedure.

In experiment 2, a subject was required to identify 50 stimulants. A series of multiple regression analyses were performed on the data to determine the influence of age, gender, race and smoking habits on the odor identification test scores. The results were then interpreted within the context of the individual's occupation, general health, and psychological state. Age and gender were considered as related to the diminishment of an individual's ability to smell over time.

At the cited pages 16-18, Doty is describing interpretation of the results of the odor identification test within the context of the individual's occupation, general health, and psychological state. Doty further discloses that an individual's age and gender were also taken into consideration when evaluating the test results of the odor identification test, which results related to the diminishment of an individual's ability to smell over time. Doty provides norms (normal test scores) based on the results of the stimulant identification study for male and female age groups (Tables 1 and 2), that relate to olfactory ability, that is anosmic (total inability to perceive qualitative odor sensations), microsmic (decreased smell ability), or normosmic ability to smell a substance.

Doty merely provides information related to a person's ability to smell and to identify odors — *not* to any physiological effect of odors.

Doty provides no basis for the Examiner's conclusion that the use of odorant sources other than the particular commercially identified odorants would be highly unpredictable between females based on Doty's disclosure is clearly unsupported.

Applicant has provided a sufficiently enabling disclosure to meet the requirements of 35 U.S.C. 112, first paragraph. Applicant's disclosure provides reasonable assurance to one skilled in the art that odorant mixtures other than the disclosed commercial sources of the

MKE/789324.1

USSN 09/211,507

Response After Final

odorants will possess the indicated utility and provide the stated effect. That is, Applicant's submit that the specification is sufficiently enabling for one of ordinary skill in the art to make and use the invention disclosed and claimed without undue experimentation.

The claims are limited to certain mixtures of odorants that alter blood flow to the vagina and thus do not call for just any odorant.

Applicant has described sources of commercial odorants, which are exemplary, that are within the scope of the claims. As evidenced by the information provided in Applicant's previous response, known methods in the art can be readily used for identifying and preparing odorants within the scope of the claims. Applicant has also described screening odorants for effectiveness in altering blood flow to the vagina in the specification at pages 7-8, and in the Example.

Applicant has fully described an embodiment of his invention and the manner for ascertaining effectiveness. Sources of the recited odorants other than the particular commercial forms disclosed by Applicant could be readily identified and used to practice the claimed invention without undue experimentation.

The character of the particular odorants recited in the claims is well-delineated and a working example is provided. It would be a routine matter for one of ordinary skill to obtain and employ other sources of the recited odorants, and readily determine without undue experimentation whether the odorant works or not.

Applicant has provided a sufficiently supporting disclosure, both through the working example and descriptive discussion, to teach those of ordinary skill in the art how to make and use the invention as broadly as it is claimed, and to show that the claimed odorant mixtures are useful in altering blood flow to the vagina of a female individual.

Applicant believes that the present disclosure is fully enabling for odorants other than the particular commercial sources described, and requests that the Examiner withdraw the rejection.

Rejections under 35 U.S.C. §112(2).

The Examiner rejected the Claims 1, 2, 4-6, 9-11 35, and 39-44 under Section 112(2) for the use of indefinite claim language. Insofar as this rejection is maintained, this rejection is respectfully traversed.

MKE/789324.1

USSN 09/211,507

Response After Final

The Examiner rejected Claim 10 on the basis that it is unclear as to what a 25-55 decismel unit concentration refers to. It is submitted that the claim is clear in its meaning. However, Claims 9 and 10 have been amended to clarify that it is the concentration of the odorant at which it is administered to the female individual.

As indicated in Applicant's previous response, this is clearly described in the specification at page 5, lines 4-7 (emphasis added):

...it is preferred that *the subject individual is presented with the odorant at a superthreshold concentration (e.g., about 25-55 decismel units)*, but not irritative level,...

The Examiner is also directed to Applicant's issued patent, USP 6,106,837, and Claims 1-2, for example, which demonstrate that the claim language presently used is acceptable and well understood in the art and by the USPTO (emphasis added).

1. A method of alleviating cephalic pain caused by a headache in a person, consisting essentially of:
administering to the person by inhalation, a green apple odorant in an amount and for a time period effective to alleviate the cephalic pain; the odorant being hedonically pleasant to the person; wherein a suprathreshold but non-irritant amount of the odorant is administered.
2. The method according to claim 1, *wherein the concentration of the odorant is about 25-55 decismel units.*

Accordingly, it is submitted that Claim 10 is clear in its meaning, and withdrawal of this rejection is requested.

The Examiner further rejected the claims under Section 112, second paragraph, stating that Applicant fails to adequately define the metes and bounds of the mixtures of odorants claimed, i.e., fails to use definite claim language. The Examiner maintains that the odorants are not well understood nor adequately delineated making the claims ambiguous and unclear, contending that the claimed odorants are highly subjective with respect to the actual odors being encompassed due to variations in recipes of pumpkin pie or banana nut bread, variations in baby powder manufacturers, variations in cucumber brands, species, age/ripeness and geographic locations, a "distinct odor" of Good and Plenty™ from other licorice based products, and a "distinct odor" of milk chocolate compared to dark chocolate. The Examiner also restated his reasoning that the odorants instantly disclosed and claimed have unusual functional effects, and thus should be limited to the disclosed commercial sources.

MKE/789324.1

USSN 09/211,507

Response After Final

The Examiner has adopted a claim interpretation that ignores the way the terms are used in the art and in the specification.

The claims employ well-known language conventionally used in the art to which the invention pertains. Applicant believes the Examiner's interpretation of the terms "licorice-based odorant," "banana nut bread odorant," "cucumber odorant," "lavender odorant," "pumpkin pie odorant," "baby powder odorant," and "chocolate odorant," ignores the understanding in the art and the meaning given to the terms in other patents, and fails to take into account the description provided in the specification to define those terms.

The specification qualifies the odorants as those that effectively alter blood flow to the vagina when inhaled by a female individual, and this feature is recited in the claims.

In the previous response, Application submitted evidence of how one skilled in the art uses and understands the terms "licorice-based odorant," "cucumber odorant," "lavender odorant," "pumpkin pie odorant," "baby powder odorant," and "chocolate odorant," and to show the acceptance of these terms in the art, as well as the use and construction applied to these terms by the USPTO. For example, three U.S. patents issued to Applicant use these terms and are in the same U.S. class (424) as the patent application under consideration.

Importantly, U.S. Patent 5,885,614 (Hirsch) (Use of odorants to treat male impotence, and article of manufacture therefor) describes a situation similar to the present application where odorants are used and claimed in a *method and article of manufacture for increasing penile blood flow in a male individual*. Commercial sources for the odorants are provided in the specification at col. 2, lines 40-43. Several of the presently claimed odorants are recited in the claims, for example, Claims 1, 2 and 4 below (emphasis added):

1. A method of increasing penile blood flow in a male individual, comprising:
administering to the male by inhalation of an odorant in an amount effective to increase penile blood flow; the odorant selected from the group consisting of orange, a mixture of lavender and pumpkin pie a mixture of doughnut and black licorice, a mixture of pumpkin pie and doughnut lily of the valley, black licorice, a mixture of doughnut and cola, a mixture of black licorice and cola, a mixture of lavender and doughnut, chocolate, strawberry, rose, green, apple, parsley, peppermint, musk, lavender, vanilla, cranberry, pink grapefruit, floral, baby powder, oriental spice, cinnamon buns, roasting meat, cheese pizza, doughnut, cola, pumpkin pie, and buttered popcorn.
2. A method of increasing penile blood flow in a male individual, comprising:
administering to the male by inhalation of an odorant in an amount effective to increase penile blood flow; the odorant selected from the group consisting of a mixture of lavender and

MKE/789324.1

USSN 09/211,507

Response After Final

pumpkin pie, a mixture of doughnut and black licorice, and a mixture of pumpkin pie and doughnut.

4. An article of manufacture, comprising:
- (a) an odorant as recited in claim 1 packaged within a container, wherein the odorant when inhaled by a male individual is effective to increase penile blood flow; and
 - (b) instructions for use of the odorant according to the method of claim 1.

U.S. Patent 5,759,521 (Hirsch) (Method of altering perception of relative space of an area) identifies a cucumber odorant as useful (col. 1, line 66 to col. 2, lines 3 and lines 31-34:

"...a substance having the characteristics of a green apple odorant, cucumber odorant, or seashore odorant is administered to a patient to cause the patient's perception of a confined area to become altered and expanded.."

and commercial sources of the odorants (at col. 2, lines 45-47).

U.S. Patent 6,106,837 (Hirsch) (Method of treating headaches, and article of manufacture therefor) identifies lavender odorant as useful and provides several commercial sources of the odorants (at col. 3, lines 31-37):

An example of such an odorant is a substance having the characteristic of a green apple odor such as isoamyl isovalerate. Other useful odorants include, for example, banana, peppermint, and lavender. Such odorants are available commercially, for example, from International Flavors and Fragrances, Inc. (IFF, New York, N.Y.), Energy Essentials, Aroma Tech, and as essential oils.

U.S. Patent 4,463,016 (Burgess) (Method for the treatment of razor bumps) describes a topical composition that can include a "fragrance such as cucumber fragrance No. 24." See col. 2, line 59. The odorant is also recited in Claim 6 below (emphasis added):

1. A method for the treatment of razor bumps which comprises topically administering to an individual suffering from razor bumps an effective amount of a compound of the Formula: [formula] wherein R₁ and R₂ are C₁-C₇ alkyl in combination with a vehicle which facilitates topical application of the compound of Formula I.

6. The method according to claim 5 wherein said vehicle is composed of ingredients selected from the group consisting of propylene glycol, purified water, lanolin, sodium stearate, polyethylene glycol monostearate, sesame oil, cetyl alcohol, methyl paraben, propyl paraben, camphor and cucumber fragrance.

Also importantly, the Doty publication (Philadelphia Sensorics, 1983) -- cited by the Examiner -- lists licorice, chocolate, and pumpkin pie odorants, among others (Doty at page 7).

MKE/789324.1

USSN 09/211,507

Response After Final

Such use clearly shows that one skilled in the art uses and understands the terms "licorice-based odorant," "banana nut bread odorant," "cucumber odorant," "lavender odorant," "pumpkin pie odorant," "baby powder odorant," and "chocolate odorant." Equally important, the above patents, particularly USP 5,885,614 issued by the USPTO with claims to a method and article of manufacture to increase penile blood flow, demonstrate that the presently used odorant terms are accepted and well understood in the art and by the USPTO. As such, the Examiner's interpretation of the claims is overbroad in view of how the term is used and understood by one skilled in the art and conflicts with the meaning give to identical terms in other patents from analogous art.

The terms licorice, cucumber, lavender, pumpkin pie, baby powder, and chocolate odorants have been utilized in various contexts including Applicant's own issued patents as well as other issued patents and publications — *including the cited Doty publication* (see page 7 listing licorice, chocolate, pumpkin pie odorants), for example.

The Examiner improperly interprets the claim limitations as being overbroad.

One skilled in the odorant arts reading the claims would understand the metes and bounds of those terms in the claims when read in light of the specification, which sets forth examples for such odorants, and in view of the knowledge in the art, as evidenced by Applicant's issued patents and Doty's publication, among others. It is respectfully submitted that the nature and identity of the recited odorants is not ambiguous to one skilled in the odorants arts.

One of ordinary skill in the art would readily identify and use both synthetic and natural sources of the recited odorants other than the commercial sources of odorants disclosed in the specification according to the claimed method.

As such, Applicant believes that the claims are clear in their meaning and that the language of the claims is definite and correct, and requests that the Examiner withdraw the rejection.

Extension of Term. The proceedings herein are for a patent application and the provisions of 37 CFR § 1.136 apply. Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that Applicant has

MKE/789324.1

USSN 09/211,507

Response After Final

inadvertently overlooked the need for a petition for extension of time. If any extension and/or fee is required, please charge Account No. 23-2053.

Based on the amendments and above remarks, it is submitted that the present claims are in condition for allowance, and notification to that effect is respectfully requested.

Respectfully submitted,

Kristine M Strodthoff

Dated: September 6, 2002

Kristine M. Strodthoff
Registration No. 34,259

P.O. ADDRESS:

WHYTE HIRSCHBOECK DUDEK S.C.
111 East Wisconsin Avenue, Suite 2100
Milwaukee, Wisconsin 53202
(414) 273-2100

Enclosures: Replacement claim sheets and blacklined version of claims showing amendments

MKE/789324.1

10

Replacement Claims (USSN 09/211,507)**WHAT IS CLAIMED:**

1. A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant effective to alter blood flow to the vagina;
wherein the odorant is selected from the group consisting of a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a mixture of lavender and pumpkin pie odorants, a mixture of baby powder and chocolate odorants, and combinations thereof.
2. The method of claim 1, wherein administering the odorant is effective to increase blood flow to the vagina of the female individual by about 10-30%.
4. The method of claim 1, wherein administering the odorant is effective to increase blood flow to the vagina of the female individual by about 4-15%.
5. A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina;
wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorant, a mixture of a lavender and pumpkin pie odorant, a mixture of a baby powder and chocolate odorant, and combinations thereof.
6. A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina,
the odorant comprising a mixture of licorice-based and cucumber odorants; wherein
administering the odorant is effective to decrease blood flow to the vagina of the female individual by about 10-20%.

MKE/618834.8

1

USSN 09/211,507
Amended Claims (Sept. 2002)
Inventor: Alan R. Hirsch
Attorney Docket: INS-31061

Replacement Claims (USSN 09/211,507)

9. (amended) The method of claim 1, wherein the odorant is administered at a concentration effective to provide a suprathreshold but not irritant amount of the odorant.
10. (amended) The method of claim 9, wherein the odorant is administered at a concentration of about 25-55 decismel units.
11. The method of claim 1, further comprising: having the female individual inhale the odorant for about 1-3 minutes.
35. The method of Claim 43, whereby inhalation of the odorant increases the blood flow to the vagina by about 10-30 %.
39. The method of Claim 43, wherein the odorant is provided in a delivery device selected from the group consisting of a vial, jar, pouch, can, bottle, blister pack, and a scratch-and-sniff odor patch containing microcapsules of the odorant.
40. The method of Claim 43, wherein the odorant is provided in a form selected from the group consisting of a cloth scented with the odorant, an aerosol spray, a pump-type spray, a nasal spray, a liquid or solid form of the odorant contained in a vessel having a cap, a liquid or solid form of the odorant contained in a blister pack, and microcapsules of the odorant contained in a scratch-and-sniff odor patch.
41. The method of Claim 43, wherein the odorant is provided in the form of a cream or a cologne.
42. The method of Claim 43, wherein the odorant is provided in a liquid form contained in a dispenser.

MKE/618834.8

Replacement Claims (USSN 09/211,507)

43. A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina,
wherein the odorant comprises a mixture of a licorice-based odorant and a cucumber odorant.
44. A method for increasing blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to increase blood flow to the
vagina by about 10-30%; wherein the odorant is selected from the group consisting of a mixture
of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber
odorants, a mixture of lavender and pumpkin pie odorants, a mixture of baby powder and
chocolate odorants, and combinations thereof.

MKE/618834.8

3

USSN 09/211,507
Amended Claims (Sept. 2002)
Inventor: Alan R. Hirsch
Attorney Docket: INS-31061

Blacklined Claims (USSN 09/211,507)**WHAT IS CLAIMED:**

1. A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant effective to alter blood flow to the vagina;

wherein the odorant is selected from the group consisting of a mixture of licorice-based and banana nut bread odors, a mixture of licorice-based and cucumber odors, a mixture of lavender and pumpkin pie odors, a mixture of baby powder and chocolate odors, and combinations thereof.

2. ~~(amended)~~—The method of claim 1, wherein administering the odorant is effective to increase blood flow to the vagina of the female individual by about 10-30%.

4. ~~(amended)~~—The method of claim 1, wherein administering the odorant is effective to increase blood flow to the vagina of the female individual by about 4-15%.

5. ~~(amended)~~—A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina;
wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorant, a mixture of a lavender and pumpkin pie odorant, a mixture of a baby powder and chocolate odorant, and combinations thereof.

6. ~~(amended)~~—A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina,
the odorant comprising a mixture of licorice-based and cucumber odors; wherein
administering the odorant is effective to decrease blood flow to the vagina of the female individual by about 10-20%.

MKE/789393.1

1

USSN 09/211,507
Amended Claims (Sept. 2002)
Inventor: Alan R. Hirsch
Attorney Docket: INS-31061

Blacklined Claims (USSN 09/211,507)

9. (amended) The method of claim 1, wherein the odorant is administered at a concentration of
the odorant is effective to provide a suprathreshold but not irritant amount of the odorant.

10. (amended) The method of claim 9, wherein the odorant is administered at a concentration of
the odorant is at about 25-55 decismel units.

11. The method of claim 1, further comprising: having the female individual inhale the
odorant for about 1-3 minutes.

35. The method of Claim 43, whereby inhalation of the odorant increases the blood flow to
the vagina by about 10-30 %.

39. The method of Claim 43, wherein the odorant is provided in a delivery device selected
from the group consisting of a vial, jar, pouch, can, bottle, blister pack, and a scratch-and-sniff
odor patch containing microcapsules of the odorant.

40. The method of Claim 43, wherein the odorant is provided in a form selected from the
group consisting of a cloth scented with the odorant, an aerosol spray, a pump-type spray, a nasal
spray, a liquid or solid form of the odorant contained in a vessel having a cap, a liquid or solid
form of the odorant contained in a blister pack, and microcapsules of the odorant contained in a
scratch-and-sniff odor patch.

41. The method of Claim 43, wherein the odorant is provided in the form of a cream or a
cologne.

42. The method of Claim 43, wherein the odorant is provided in a liquid form contained in a
dispenser.

MKE/789393.1

Blacklined Claims (USSN 09/211,507)

43. A method for altering blood flow to the vagina of a female individual, comprising:
administering to the female by inhalation of an odorant to alter blood flow to the vagina,
wherein the odorant comprises a mixture of a licorice-based odorant and a cucumber odorant.

44. ~~(amended)~~—A method for increasing blood flow to the vagina of a female individual,
comprising:
administering to the female by inhalation of an odorant to increase blood flow to the
vagina by about 10-30%; wherein the odorant is selected from the group consisting of a mixture
of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber
odorants, a mixture of lavender and pumpkin pie odorants, a mixture of baby powder and
chocolate odorants, and combinations thereof.

MKE/789393.1

3

USSN 09/211,507
Amended Claims (Sept. 2002)
Inventor: Alan R. Hirsch
Attorney Docket: INS-31061